



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of Veterinary Feed Directive (VFD) drugs and animal feeds containing VFD drugs.

DATES: Submit electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Feed Directive--21 CFR 558; OMB Control Number 0910-0363--Extension

With the passage of the Animal Drug Availability Act, Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving state pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) was tailored to the unique circumstances relating to the distribution of medicated feeds. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible.

On December 12, 2013, FDA published a proposed rule in the Federal Register (78 FR 75515) intended to improve the efficiency of FDA's VFD program. The provisions included in the proposed rule were based on stakeholder input received in response to solicitations for public comment, including an advance notice of proposed rulemaking on March 29, 2010 (75 FR 15387), and draft text of proposed amendments to the current VFD regulations on April 13, 2012 (77 FR 22247).

While FDA intends to finalize the VFD rulemaking in 2015, the current information collection request supporting the program expires on December 31, 2014. At this time, the burden for this information collection remains unchanged.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|------------------------------------|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 558.6(a)(3) through (a)(5) | 15,000 | 25 | 375,000 | 0.25 (15 minutes) | 93,750 |
| 558.6(d)(1)(i) through (d)(1)(iii) | 300 | 1 | 300 | 0.25 (15 minutes) | 75 |
| 558.6(d)(1)(iv) | 20 | 1 | 20 | 0.25 (15 minutes) | 5 |
| 558.6(d)(2) | 1,000 | 5 | 5,000 | 0.25 (15 minutes) | 1,250 |
| 514.1(b)(9) | 1 | 1 | 1 | 3.00 | 3 |
| Total | | | | | 95,083 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2. --Estimated Annual Recordkeeping Burden¹

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|----------------------------|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 558.6(c)(1) through (c)(4) | 112,500 | 10 | 1,125,000 | 0.0167 (1 minute) | 18,788 |
| 558.6(e)(1) through (e)(4) | 5,000 | 75 | 375,000 | 0.0167 (1 minute) | 6,263 |
| Total | | | | | 25,051 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of time required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: September 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.